



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,582	07/25/2003	Andrew M. Kuhn	P-5802	9537
26253	7590	01/30/2007	EXAMINER	
DAVID W. HIGGET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	01/30/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TV

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/626,582	KUHN, ANDREW M.
	Examiner	Art Unit
	Pablo Whaley	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 31 October 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-34 is/are pending in the application.
  - 4a) Of the above claim(s) 1-8 and 19-34 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 9-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

**EXAMINER'S COMMENT**

In the response, filed 10/31/2006, applicant stated that the Examiner indicated claims 15 and 16 "are allowable upon entry of the above amendments." The Examiner made no such indication of allowability, as claims 15 and 16 were clearly rejected under 35 U.S.C. 101 in the previous office action.

**CLAIMS UNDER EXAMINATION**

Claims herein under examination are 9-18. Claims 1-8 and 19-34 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

**CLAIM REJECTIONS - 35 USC § 101**

Applicant's arguments, filed 10/31/2006, that claims 9-18 are now drawn to statutory subject matter are not deemed to be persuasive. This rejection is maintained for the reasons set forth below.

Claims 9-18 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 9-18 are now directed to a "tangible medium containing

instructions that when executed by one or more processors performs a method for analyzing numerical data pertaining to a sample assay." It is noted that the instant method for analyzing numerical data "pertaining to a sample assay" do not recite any steps that result in a physical transformation of matter (e.g. obtaining data from a sample assay), and thus encompass non-physical (i.e. *in-silico*) method steps which are non-statutory. It is also noted that claim 9 now results in "indicating whether said sample assay has a predetermined characteristic." However, this limitation does not constitute a "tangible result", as said "indicating" may occur within the body of a computer program and never be conveyed to a user [See 112 2<sup>nd</sup> rejection below]. Therefore, the "tangible medium" for analyzing numerical data does not impart structural and functional interrelationships between the computer-executable instructions and other computer software and hardware components such that functionality is realized (i.e. communication of an output to a user).

For these reasons, the claimed method steps remain interpreted as non-functional descriptive material. Non-functional descriptive material stored on a computer-readable medium is not statutory subject matter (e.g. music stored on a compact disk). This rejection could be overcome by amending the method steps of the claimed tangible medium to recite that a result is "displayed" or "outputted" (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "indicating whether said sample assay has a predetermined characteristic." As the specification does not define or fully and completely describe "indicating" for carrying out the intended function, it is unclear in what way the characteristic of said sample assay is actually indicated and to whom or what. Clarification is requested.

**CLAIM REJECTIONS - 35 USC § 102**

Claims 9-18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yang et al. (US 6,216,049; Issued: Apr. 10, 2001).

Applicant's arguments, filed 10/31/2006, that Yang et al. do not teach all elements of the claimed invention, specifically with regards to claims 9-14, are not persuasive for the reasons set forth below. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not show how the amendments avoid the teachings of Yang et al. This rejection is therefore maintained, and newly applied to claims 15-18 as necessitated by amendment.

Claim 9 requires steps of assigning values, correcting values, comparing corrected values to a threshold, and again correcting the corrected values based on corrected values that exceed the threshold. The Examiner maintains that Yang et al. indeed teaches assigning values, correcting values, and comparing corrected values to a threshold [Ref. Claim 1], wherein said assigning comprises comparing each of the data values with adjacent data values to determine values that are greater than a predetermined amount and subsequent adjusting of said data values [Ref. Claim 3], which is indeed a teaching for a subsequent correction of initial values, as in claim 9. Yang et al. also provides for a computer-readable medium for performing the claimed method steps [Ref. Claim 12], as in claim 9.

Claims 10-14 have been amended to require steps directed to arranging data values in a "time-ordered sequence", calculating a correction value, adjusting numerical values in relation to adjacent values, and calculating an average value and comparing to a threshold value. Yang et al. clearly teach arranging data values in a "time-sequence" [Fig. 5] and [Ref. Claim 2], as in claim 10. Yang et al. also teach comparing data values with adjacent data values and adjusting of said data values to produce respective values assigned to subsequent data values [Ref. Claim 3], as in claims 11 and 12, and calculating average values and comparing average value to a threshold value [Ref. Claims 4 and 5], as in claims 13-14. Therefore, the critical limitations recited in amended claims 10-14 have not been given patentable weight over the teachings of Yang et al. For these reasons and those set forth in the previous office action, the Examiner maintains that Yang et al. indeed teaches all of the limitations of claims 9-14.

Furthermore, this rejection is newly applied to claims 15-18, as necessitated by amendment. Yang et al. teach combining data values which have previously been corrected and adjusted [Ref. Claims 1 and 3], as in claim 15; a secondary step of comparing each of the data values with adjacent data values to determine values that are greater than a predetermined

amount (i.e. reference value) [Ref. Claim 3], as in claim 16; assigning and arranging said data values in a sequence representative of said respective times [Ref. Claim 2], as in claim 17; and provides for an indication of values that exceed a threshold [Col. 13, lines 55-65] and [Ref. Claim 3], as in claim 18. For these reasons and those set forth above, Yang et al. teach all of the limitations of claims 9-18.

Claims 9-11, 13, 17-18, are rejected under 35 U.S.C. 102 (b) as being anticipated by Kurnik et al. (Sensors and Actuators B, 1999, vol. 60, p.19-26).

Applicant's arguments, filed 10/31/2006, that Kurnick et al. do not teach "assigning respective numerical values to the data values" are not persuasive for the reasons set forth below. This rejection is therefore maintained.

The specification does not provide any limiting definitions that would serve to illustrate in what way data values are respectively assigned to numerical values. Furthermore, applicant does not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited with regards to said "assigning numerical values to the data values." Therefore, the Examiner maintains that he has broadly and reasonably interpreted this limitation to encompass the teaches of Kurnick et al. Kurnick et al. uses a Mixture of Experts (MOE) algorithm for predicting numerical values for raw data obtained over time and assigning them to values on graph [Fig. 4]. Furthermore, the Examiner maintains that Kurnick et al. does not merely display raw data, but also provides for correction of data [Section 4.1, para. 1]; comparison of data to predefined values or thresholds, and exclusion of data that exceed predefined thresholds (i.e. secondary correction) [p.22, col. 2, paragraph 3], as in instant claims 9 and 13. algorithm is applied to the corrected data set and compared to

reference blood glucose values [Fig. 4], which correlates to second comparing data as in instant claim 9. Furthermore, as set forth in the previous office action, Kurnick et al. teaches the following aspects of the instant claimed invention:

- Indication of whether the blood glucose levels as measured by the MOE system are accurate as compared to predetermined blood glucose levels (i.e. characteristics) [Fig. 3], as in instant claim 9.
- Calculating a calibration signal based on a plurality of numerical values including elapsed time after subject calibrates the device [p.20, col. 2, para. 3], which correlates to a beginning of a sequence as in instant claim 11.
- Blood glucose (BG) input values are weighted and assigned respective time values [p. 21, Equations (6) and (7)], as in instant claim 17.
- Corrected values that exceed threshold are excluded [p.22, col. 2, paragraph 3], which correlates to a report of whether corrected numerical values exceed a threshold as in instant claim 18.

For these reasons and those set forth above, the Examiner maintains that Kurnick et al. indeed teach all of the limitations of claims 9-11, 13, 17-18.

## CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner  
Art Unit 1631  
Office: 571-272-4425

  
JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER